

Remarks

Preliminary Matters

Claims 1-3, 5-17, 19-35, and 39-49 are presented for reconsideration. Claims 4, 18, 36-38, and 50-51 have been canceled. Claims 1, 3, 5, 12, 16, 17, 19, 35, 42, 47, and 48 have been amended.

The Examiner has requested that the claim amendments be labeled as "--twice amended--", "--four times amended--", etc., but Applicant believes that this is no longer possible without contravening recently changed Rule 121. However, Applicant appreciates the benefit of the former claim labels, and to assist the Examiner, provides the following table of currently amended claims:

Claim	Amendment History
1	Amended 5 times
3	Amended 2 times
5	Amended 2 times
12	Amended 5 times
16	Amended 5 times
17	Amended 1 time
19	Amended 1 time
35	Amended 5 times
42	Amended 5 times
47	Amended 5 times
48	Amended 1 time

Rejections Under 35 U.S.C. § 103

First Rejection.

Claims 1-3, 7, 9, 10, 12, 13, 15-18, 22, 24, 25, 32-37, 39-45 and 47-50 are rejected under 35 U.S.C. § 103 as being unpatentable over Ben-Haim *et al.*, U.S. Patent No. 5,718,241 in view of Goldreyer, U.S. Patent No. 5,385,146.

Independent claim 1, 16, and 42 have been amended to distinguish the present invention over the cited art. As now claimed, the inventive catheter is operable in a dual mode, wherein either the non-contact electrodes alone, or the non-contact electrodes along with the contact electrode can be used to sense electrical information during at least a cardiac cycle. This feature is not found, nor implied, in either Ben-Haim or Goldreyer. Goldreyer discloses a contact electrode at the distal tip, but only for use as an ablation electrode (e.g., col. 4, lines 11 - 13). As the Examiner has indicated, Ben-Haim discloses a tip electrode 105 (Fig. 16), which can be used to obtain local activation data (col. 10, lines 15-25; col. 11, lines 18 - 25). However Ben-Haim does not disclose catheter operation in two modes, such that additional electrodes alone or in combination with the tip electrode could obtain electrical information. Thus, there is no teaching of two modes of catheter operation as now claimed in amended claim 1.

Support for the amendments is found at Specification page 14, lines 24 - 32, where Applicant emphasizes the optional use of contact electrode 24 along with the non-contact electrode arrays 23 to obtain electrical information from the heart. The use of non-contact locations, alternatively or together with the location of the contact electrodes can be used to define chamber geometry (Specification, page 17, lines 20 - 22).

An advantage of the combined use of the two types of electrode (the claimed second mode of operation), not disclosed in the cited art, is the ability of the data taken by the contact electrode to constrain the information determined from the non-contact electrodes (Specification, page 18, lines 1 - 4).

Independent claims 12, 35, 42, and 47 have been amended to recite the capability of at least one location sensor to provide

six degrees of location information. These claims are now believed to be allowable for the reasons discussed below with respect to the second rejection.

Second Rejection.

5 Claims 4-6, 14, 19-21, 26-31, 38, 46, and 51 are rejected under 35 U.S.C. § 103 as being unpatentable over Ben-Haim and Goldreyer in view of Martinelli, U.S. Patent No. 6,104,944. Martinelli discloses a plurality of navigated electrode elements (location elements), which are distributed along a segment of a
10 catheter and are interlaced with virtually navigable electrode elements. Martinelli further discloses a general application specific system 12 (col. 8, lines 1-12), in which it is proposed that the electrode elements used for navigation could also be used for other purposes, including mapping. Applicant's presently
15 claimed invention recites different structure for location sensors and sensing electrodes, thus avoiding the complexities of the general application specific system of Martinelli. One following Martinelli would not be motivated to add different types of devices, such as sensing devices, to a catheter disclosed therein to arrive at the claimed invention, because Mar-
20 tinelli stresses the importance of reducing wiring and sensor overhead (col. 2 lines 7-22) by utilizing the navigation elements for functions other than providing location information.

25 Martinelli is directed to a method and system for navigating a multiple electrode catheter. Although contrary to the Examiner's statement, the Applicant notes that the Martinelli system does not provide for six degrees of location information, but rather only five degrees of location information x, y, z and θ , ϕ (col. 8, lines 61 - 65).

30 Martinelli explains (col. 10, lines 13 - 25), that relative delta locations are determined using positional displacement co-

ordinates to obtain a location for the navigated electrode element N_1 relative to N_2 , for example. As to the claimed sixth degree of freedom claimed herein, the Examiner is able to assert only that the sixth degree of freedom according to Martinelli is a substantially zero component. If so, such an arrangement would not provide practical location information about the sixth axis if this component were non-zero, and nor could relative displacements between different navigated electrode elements be determined in the sixth axis. It is urged that Martinelli does not really provide a practical system for obtaining location data concerning the sixth axis as claimed herein.

Claims 3, 17, 35, and 48 have been amended in order to incorporate the limitations of claims 4, 18, 36-38, and 50-51, respectively, and to more particularly claim the invention, wherein the location elements in the catheter are exclusive of the sensing electrodes, the sensing (non-contact) electrodes being enclosed between two location sensors, as shown in Applicant's Fig. 3 (location sensors 28 and 48). Claims 4, 18, 36 - 38, and 50 - 51 have been canceled. Claims 5 and 19 have been amended to adjust dependencies.

Regarding claims 14 and 46, their respective independent base claims 12 and 42 have been amended. Claims 14 and 46 are believed to be allowable as depending from an allowable base claim.

Third Rejection.

Claims 8, 11, and 23 are rejected under 35 U.S.C. § 103 as being unpatentable over Ben-Haim and Goldreyer in view of Swanson et al., U.S. Patent No. 6,171,306. The Examiner asserts that Swanson discloses a bipolar tip electrode.

Claims 8, 11, and 23 are now believed to be allowable as pending from an allowable base claim.

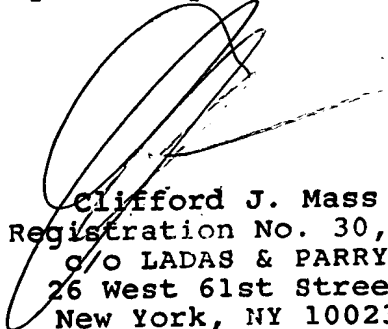
**Concluding Matters**

It is believed that the amendments and remarks presented hereinabove are fully responsive to all the grounds of rejection and objections raised by the Examiner, and that the Application is now in order for allowance.

Applicant thanks the Examiner for his thorough consideration of the Application and appreciates the careful analysis of the art cited therein.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. 12-0425. A duplicate copy of this sheet is enclosed.

Respectfully submitted,


Clifford J. Mass
Registration No. 30,086
c/o LADAS & PARRY
26 West 61st Street
New York, NY 10023
(212) 708-1890